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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,401	07/18/2003	Craig A. Rosen	PZ020P2C1	6102

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,401	ROSEN ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-33 and 48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-33 and 48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24-33 and 48-57 are pending in this application.

Applicant's arguments filed 9/28/2004 have been fully considered but they are not completely persuasive. Any rejection not repeated below has been withdrawn.

The IDS filed 9/28/2004 has been entered and considered. An initialed copy of the PTO-1449 form is enclosed with this action.

Applicant's assertions and evidence regarding the original disclosure date of the claimed sequence have been considered, and the priority date for claims drawn to SEQ ID NO: 145 is 11/7/1997.

Claims 24-33 and 48-57 remain rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or a well established utility for the reasons set forth in the previous office action.

The rejected claims are drawn to polypeptides of SEQ ID NO: 145, or the protein from the related deposit HFVAB79.

Applicant's arguments have been carefully considered, but are not persuasive. Applicant is correct in noting that a diagnostic test for a specific disease is not specifically required to establish utility- the Examiner was setting forth the facts regarding the elected sequence, and the information provided in the specification.

Applicant cites In re Brana, and MPEP 2107.01 to support the argument that the need for further research does not obviate patentability. Applicant's argument has been fully considered, however, the section of the MPEP cited by Applicant makes clear that there was in vitro testing of the claimed compound for a specific, substantial and credible activity. No in vitro tests for any specific activity are set forth in the specification for the claimed polypeptides. In the case of In re Brana, the specification disclosed highly similar chemical compounds which were known to have a specific and well established utility against cancer. The instant specification discloses no similar polypeptides having any well established utilities.

Applicant disagrees with the assessment that the laundry list of possible uses is not probative of a specific, substantial and credible utility for the claimed polypeptides. Applicant points to MPEP 2107.02 wherein if one credible assertion of utility is made, then utility is

established. However, the length and diversity of potential activities, and utilities enumerated in the specification leaves it to one of skill in the art to determine which is credible. The Examiner submits that such determinations would require further inventive research beyond the disclosures of the specification.

Applicants further argue that they disclose a biological activity that reasonable correlates to a disease or condition, however, Applicant merely points back to the long list of potential diseases, and the indication that the molecule "may" be secreted from the cell. No biological activity of the polypeptide itself is disclosed in the specification. Therefore, there can be no correlation to a disease or condition.

Applicant submits art published post filing in support of their position, however, the disclosures of this art go beyond the experiments proposed in the specification, and the art fails to shed light on any utility known at the priority date accorded the claims.

As set forth previously, the claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification identifies SEQ ID NO: 145, the elected polypeptide sequence, as being related to "gene 7" at pages 28-30. SEQ ID NO: 145 is also referenced in the table at page 276. At pages 28-30, the specification asserts that the polypeptide sequence encoded by "gene 7" is expressed primarily in the liver and testes.

At pages 28-30 the specification lists a variety of potential activities and tissue "specificities" that may be related to the elected sequence. Activities and specificities for the DNA and/or encoded protein listed in this section include: hepatic, endocrine and reproductive disorders, as well as immune system and hematopoetic system disorders. At no point is the specifically elected sequence tested for any of the listed associations, activities or expression patterns. At no point is a diagnostic test for any disease developed such that the elected sequence is shown to be linked diagnostically to a particular disease. Each of the above activities is very

different, and they are substantially non-overlapping. One of skill in the art would not readily be able to determine a use for the claimed sequence upon reading the specification.

At pages 29-30, the specification sets forth a laundry list of potential uses for any protein involved in cell growth and differentiation, including "detection, treatment, and./or prevention of hepatoblastoma, jaundice, hepatitis or liver metabolic diseases and conditions that are attributable to the differentiation of hepatocyte progenitor cells" without specifically linking the claimed protein to any particular type of disorder, activation pathway or other activity. The list of potential uses include the disparate categories of testicular function, other reproductive disorders, inflammatory disorders, cancer, as well as the categories of "hypoproliferative disorders" and "Infectious diseases". Each of these categories of disease have widely varying etiology, causes, and treatments, and the specification provides no particular evidence linking the claimed protein to any particular disease, or even class of diseases.

The laundry list of potential activities pointed to by Applicant all are general in nature, many are conflicting, many have widely varying causes or effects such that upon reading the specification, one of skill in the art would not be readily able to determine a specific substantial and credible utility for the claimed polypeptides.

The specification was further probed for information as to a specific substantial and credible utility for the claimed peptide. At page 276, in the table, SEQ ID NO: 145 is identified as being encoded by SEQ ID NO: 17. The table asserts that the polypeptide has a signal sequence beginning with amino acid 1, and ending with amino acid 15, and asserts that the secreted portion would be from amino acids 16-194. This information was all generated by computer analysis and has not been validated by producing the polypeptide in vitro and observing cleavage and secretion of the actual sequence. No such experiments are set forth in the specification as filed. No particular activities or functions are specifically linked to any form of the polypeptides being claimed.

Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities.

For example, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Iyer et al. Genome Biology 2001 2 (12) pages 1-11; and Baker et al. Science, October, 2001, Vol. 294 pages 93-95. (Each of record in parent application 09/974879) However, this level of factual evidence is absent here.

General uses of polypeptides set forth in the specification, as filed, treatment or prevention of unidentified diseases, identification of binding partners, use in production of antibodies to the polypeptides, etc. These general uses are not specific and substantial, as they do not require any one particular sequence. Further, they provide no specific information about any one sequence. For example, for the asserted utility of prevention, diagnosis or treatment of a disease, one would need to know what disease is linked to the polypeptide, and in what way- i.e. does the disease result from too much or too little of the claimed polypeptide. Therefore one of ordinary skill in the art would have to perform additional tests to determine which specific disease could be linked, how it could be linked, and whether or not the peptide itself can be used to treat, prevent or diagnose that disease.

The need for such further research and experimentation clearly indicates that the asserted utilities for the polypeptides are not disclosed and therefore are not specific, substantial and credible utilities Further no well established utility is supported for any one polypeptide. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and

applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the claimed polypeptides such that another non-asserted utility would be well-established for the compounds.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 24-33 and 48-57 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

MARY K. ZEMAN
PRIMARY EXAMINER
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2/4/05